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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,667

Applicant(s)

MERRIL, CARL

Examiner

Ethan Whisenant, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

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DETAILED ACTION

SEQUENCE RULES

1. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

CLAIM REJECTIONS UNDER 35 USC § 102

3. Claim(s) 24-25 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Ray et al. [US 5,650,267 (1997)].

Claim 24 is drawn to a bimolecular complex. **Claim 25** is drawn to a method of identify a target biomolecule in an assay comprising the step of forming the bimolecular complex of Claim 24 on a support.

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Ray et al. (267') teach a bimolecular complex comprising all of the limitations of Claim 24. In addition, Ray et al. (267') teach a method of identify a target biomolecule in an assay comprising the step of forming the bimolecular complex of Claim 24 on a support.

35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 103

5. Claim(s) 1-2, 4, 6-10, 13-15, 19-20, 22 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer et al. [WO 97/00329 (1997)] in view of Ray et al. [US 5,650,267 (1997)].

Claims 1, 13 and 22 is/are drawn to a method of identifying the presence of a biomolecule on a support which method comprises five defined steps.

Bayer et al. teach a method of identifying the presence of a biomolecule on a support comprising all of the steps recited in Claims 1, 13 and 22 except these authors do not teach correlating the replication of the phage with the presence of the target biomolecule. However, Ray et al. in 267' teach a very similar assay using bacteriophage wherein the replication of the phage is indicative of the presence of a target biomolecule. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Bayer et al. wherein the replication of the phage is indicative of the presence of a target biomolecule. The motivation for making this modification is provided by Ray et al. in 267' who teaches in Column 9, lines 46-48 "In this way, the presence of the molecule-of-interest can be determined and quantitated by the relative infectivity of the phage."

Claim 2 is drawn to an embodiment of the method of Claim 1 wherein the biomolecule

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(i.e. the target molecule) is selected from a defined group which includes proteins, nucleic acids and lipids.

Note that Ray et al. in 267' teach that the molecule of interest may be proteins, nucleic acids and/or lipids, see for example, Column 3, beginning at about line 49. Also note that Bayer et al. teach that the molecule of interest may be any ligand which can be biotinylated including proteins and/or nucleic acids.

Claim 4 is drawn to an embodiment wherein the support is selected from a defined group consisting of a chromatography resin.

Bayer et al. teach this limitation, see for example, at least the first full paragraph on page 10. Also, note that Bayer et al. teach that "any solid support used in the art is suitable" to practice their invention. Finally note that absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Claim 6 is drawn to an embodiment of the method of Claim 1 wherein the unbound population of phage are removed by washing with a buffer. **Claim 10** is drawn to an embodiment of the method of Claim 1 further comprising the step of isolating at least one phage from the replicated population of phage.

Bayer et al. teach these limitations. See, for example, Bayer et al., page 12, the first full paragraph.

Claim 7 is drawn to an embodiment of the method of Claim 1 wherein the bound population of phage are replicated on a lawn of host bacteria. **Claim 8** is drawn to an embodiment of the method of Claim 1 wherein the bound population of phage is overlaid with a bacterial strain that is host for the phage. **Claim 9** is drawn to an embodiment of the method of Claim 1 wherein the target biomolecule is detected by observing bacterial cell lysis.

Ray et al. in 267' teach these limitations. See, for example, Column 4, beginning at about line 20–line 65.

Claim 14 is drawn to an embodiment of the method of Claim 13 wherein the protein is

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joined to the phage by a linker.

Ray et al. in 267' teach these limitation wherein these authors teach that two-third of the gpV protein may be substituted for by a protein which can be displayed on the surface of the phage and bind to a target molecule of interest. Here the truncated gpV protein is considered to be the linker. See, for example, the "Summary of the Invention" which begins in Column 2.

Claim 15 is drawn to an embodiment of the method of Claim 13 wherein the protein is avidin or streptavidin or a derivative thereof. **Claim 20** is drawn to an embodiment of the method of Claim 14 wherein the protein is avidin or streptavidin or a derivative thereof.

Ray et al. in 267' teach this limitation wherein these authors teach that two-third of the gpV protein may be substituted for by a protein which can be displayed on the surface of the phage and bind to a target molecule of interest. Here the truncated gpV protein is considered to be the linker. See, for example, the "Summary of the Invention" which begins in Column 2. Furthermore, Ray et al. in 267' teach that essentially any protein may be attached to the truncated gpV protein in order to act as the "target molecule" and specifically state that the "target molecule is a protein such as an enzyme, enzyme substrate, immunoglobulin, or binding fragment thereon, hormone, ligand, toxin, growth factor, cytokine, receptor, or a fragment or analog of any such protein." Admittedly, Ray et al. in 267' do not explicitly state that the protein is avidin or streptavidin or a derivative thereof. However, absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Claim 19 is/are drawn to a method of identifying the presence of a biomolecule on a support which method comprises five defined steps and wherein the molecule present on the surface of the phage is a binding protein that binds to biotin.

Bayer et al. teach a method of identifying the presence of a biomolecule on a support comprising all of the steps recited in Claim 19 except these authors do not teach correlating the replication of the phage with the presence of the target biomolecule. However, Ray et al. in the 267' patent teach a very similar assay using bacteriophage wherein the replication of the phage is indicative of the presence of a target biomolecule. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Bayer et al. wherein the replication of the phage is indicative of the presence of a target biomolecule. The motivation for making

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this modification is provided by Ray et al. in 267' who teaches in Column 9, lines 46-48 "In this way, the presence of the molecule-of-interest can be determined and quantitated by the relative infectivity of the phage."

In addition, it is noted that Ray et al. in 267' do not explicitly state that the protein is avidin or streptavidin or a derivative thereof (i.e. a binding protein that binds to biotin). However, Ray et al. in 267' do teach that two-third of the gpV protein may be substituted for by a protein which can be displayed on the surface of the phage and bind to a target molecule of interest. Here the truncated gpV protein is considered to be the linker. See, for example, the "Summary of the Invention" which begins in Column 2. Furthermore, Ray et al. in 267' teach that essentially any protein may be attached to the truncated gpV protein in order to act as the "target molecule" and specifically state that the "target molecule is a protein such as an enzyme, enzyme substrate, immunoglobulin, or binding fragment thereon, hormone, ligand, toxin, growth factor, cytokine, receptor, or a fragment or analog of any such protein." Absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

6. Claim(s) 3, 23 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer et al. [WO 97/00329 (1997)] in view of Ray et al. [US 5,650,267 (1997)] as applied against Claim 1 above and further in view of Nissim et al. (1994).

Claim 3 is drawn to an embodiment of the method of Claim 1 wherein the biomolecule (i.e. the target molecule) is one of a plurality of electrophoretically separated biomolecules. **Claim 23** is drawn to essentially the same invention as claimed in Claim 3.

Note that Bayer et al. in view of Ray et al. 267' teach all of the limitations of Claims 3 and 22 except these authors do not explicitly teach an embodiment the target molecule is one of a plurality of electrophoretically separated biomolecules (i.e. Bayer et al. in view of Ray et al. 267' do not teach Western blotting). However, Nissim et al. do teach Western blotting wherein the reagent used to detect the separated protein (i.e. the target biomolecule) is a phage displaying a ligand for the separated protein. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method suggested by Bayer et al. in view of Ray et al.

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267' wherein the target biomolecule is one of a plurality of electrophoretically separated biomolecules. The motivation for making this modification would have been the motivation for performing any Western blot which is to identify the antigen the target biomolecule by reactivity and size thereby double checking the result obtained.

7. Claim(s) 5 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer et al. [WO 97/00329 (1997)] in view of Ray et al. [US 5,650,267 (1997)] as applied against Claim 1 and 4 above and further in view of Kozulic [US 5,458,760 (1995)].

Claim 5 is drawn to an embodiment of the method of Claim 4 wherein the gel has a plastic backing.

Bayer et al. in view of Ray et al. 267', as argued above, teach all of the limitations of Claim 5 except these authors do not explicitly teach an embodiment wherein the gel has a plastic backing. However, the use of plastic backing with aqueous gels to make handling of the gels more convenient was well known in the art at the time of the invention as evidenced by Kozulic. See, for example, at least, the second full paragraph in Column 4. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method suggested by Bayer et al. in view of Ray et al. 267' wherein the gel has a plastic backing. The motivation for making this modification would have been to make the handling of the gel prior to/following electrophoresis more convenient as taught by Kozulic.

8. Claim(s) 11-12 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer et al. [WO 97/00329 (1997)] in view of Ray et al. [US 5,650,267 (1997)] as applied against Claim 1 and 10 above and further in view of the Stratagene Catalog (1988).

Claim 11 is drawn to an embodiment of the method of Claim 10 wherein the method further comprises the step of incorporating the phage into a pharmaceutical product. **Claim 12** is drawn to an embodiment of the method of Claim 10 wherein the method further comprises the step of incorporating the phage into a diagnostic kit.

Bayer et al. in view of Ray et al. 267' teach all of the limitations of Claims 11 and 12 except these authors do not teach diagnostic kits (i.e. a pharmaceutical product). However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed

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to perform routine assays into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Bayer et al. in view of Ray et al. 267' with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method suggested by Bayer et al. in view of Ray et al. 267' are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

9. Claim(s) 16-18 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer et al. [WO 97/00329 (1997)] in view of Ray et al. [US 5,650,267 (1997)] and Ray et al. [US 5,679,510(1997)].

Claim 16 is/are drawn to a method of identifying the presence of a biomolecule on a support which method comprises five defined steps and wherein the molecule present on the surface of the phage is a nucleic acid.

Bayer et al. teach a method of identifying the presence of a biomolecule on a support comprising all of the steps recited in Claim 16 except these authors do not teach correlating the replication of the phage with the presence of the target biomolecule. However, Ray et al. in the 267' patent teach a very similar assay using bacteriophage wherein the replication of the phage is indicative of the presence of a target biomolecule. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Bayer et al. wherein the replication of the phage is indicative of the presence of a target biomolecule. The motivation for making this modification is provided by Ray et al. (267') who teaches in Column 9, lines 46-48 "In this way, the presence of the molecule-of-interest can be determined and quantitated by the relative infectivity of the phage."

In addition, Bayer et al. do not teach an embodiment wherein the biomolecule on a support is a target nucleic acid and the molecule present on the surface of the phage is a nucleic acid. However, Ray et al. in their 510' patent do teach that the "target molecule" (i.e. the molecule present on the surface of the phage) "may be embodied as a nucleic acid or as a substrate of an enzyme. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Bayer et al. in view of Ray et al. (267') wherein the biomolecule on a support is a target nucleic acid and the molecule present on the surface of the phage is a nucleic acid. Please note that absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation

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that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

10. Claim(s) 21 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer et al. [WO 97/00329 (1997)] in view of Ray et al. [US 5,650,267 (1997)] as applied against Claim 1 and 13 above and further in view of Wagner, Jr. [US 6,114,081 (2000)].

Claim 21 is/are drawn to essentially the same method as recited in Claims 1 and 13 except in this embodiment the biomolecule present on the solid support is a complex between the first biomolecule and a second biomolecule.

Bayer et al. in view of Ray et al. (267') do not teach an embodiment wherein the biomolecule present on the solid support is a complex between the first biomolecule and a second biomolecule. However, Wagner, Jr. do teach a detection assay wherein the solid support comprises a complex between the first biomolecule (i.e. mismatch binding protein) and a second biomolecule (i.e. a dsDNA heteroduplex fragment comprising a mismatch). See for example, at least Column 19, beginning at about line 60 through Column 29, line 43. Also note especially Column 20 beginning at about line 55 wherein Wagner, Jr. teaches "Such oligonucleotides are prepared using a detectably labeled nucleotide, preferably modified at the 5' end with a detectable label, such that they can be quantitatively detected by appropriate detection methods, preferably spectrophotometry or chemiluminescence. As used herein, the term "detectable label" is intended to include not only a molecule or label which is "directly" detected (e.g., a radionuclide or a chromogen) but also a moiety such as biotin, which is "indirectly" detected by its binding to a second (or third) binding partner one of which carries the "direct" label. In a preferred embodiment, the oligonucleotide is biotin-modified, and is detectable using a detection system based on avidin or streptavidin which binds with high affinity to biotin. The avidin or streptavidin is preferably conjugated to an enzyme, the presence of which is detected by allowing the enzyme to react with a chromogenic substrate and measuring the color developed. In view of these teachings, absent an unexpected result, it is the examiner's opinion that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method suggested by Bayer et al. in view of Ray et al. (267') wherein the biomolecule present on the solid support is a complex between the first biomolecule and a second biomolecule. Please note that absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to

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achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

11. Claim(s) 26 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray et al. [US 5,650,267 (1997)] as applied against Claim 24-25 above and further in view of Wagner, Jr. [US 6,114,081 (2000)].

Claim 26 is/are drawn to essentially the same method as recited in Claim 25 except in this embodiment the biomolecule present on the solid support is a sample of polynucleotides comprising a polymorphism.

Ray et al. (267') teach all of the limitations of Claim 26 except these authors do not teach an embodiment wherein the biomolecule present on the solid support is nucleic acids comprising a polymorphism (i.e. Ray et al. (267') do not teach detecting a polymorphism.

However, Wagner, Jr. do teach a detection assay wherein the solid support comprises a complex between the first biomolecule (i.e. mismatch binding protein) and a second biomolecule (i.e. a dsDNA heteroduplex fragment comprising a mismatch/polymorphism). In summary, Wagner, Jr. do teach a assay wherein a polymorphism is detected. See, for example, at least Column 19, beginning at about line 60 through Column 29, line 43. Also note especially Column 20 beginning at about line 55 wherein Wagner, Jr. teaches "Such oligonucleotides are prepared using a detectably labeled nucleotide, preferably modified at the 5' end with a detectable label, such that they can be quantitatively detected by appropriate detection methods, preferably spectrophotometry or chemiluminescence. As used herein, the term "detectable label" is intended to include not only a molecule or label which is "directly" detected (e.g., a radionuclide or a chromogen) but also a moiety such as biotin, which is "indirectly" detected by its binding to a second (or third) binding partner one of which carries the "direct" label. In a preferred embodiment, the oligonucleotide is biotin-modified, and is detectable using a detection system based on avidin or streptavidin which binds with high affinity to biotin. The avidin or streptavidin is preferably conjugated to an enzyme, the presence of which is detected by allowing the enzyme to react with a chromogenic substrate and measuring the color developed." In view of these teachings and absent an unexpected result, it is the examiner's opinion that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ray et al. (267') wherein the biomolecule present on the solid support is a complex between the first biomolecule and a second biomolecule (i.e. a dsDNA heteroduplex fragment comprising a mismatch/polymorphism). Please note that absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make

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the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

CONCLUSION

12. Claim(s) 1-26 is/are rejected and/or objected to for the reason(s) set forth above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



**ETHAN WHISENANT
PRIMARY EXAMINER**